**Appendix No. 2 to Request for Bids No. 01/WPD107/2020**

#### ..................................., on .............. .............

*(place) (date)*

**CONTRACTOR**

……………………………………….

*(name/registered office/address/tax ID (NIP) of the Contractor)*

**AWARDING ENTITY:**

WPD Pharmaceuticals sp. z o. o.

ul. Żwirki i Wigury 101,

02-089 Warszawa,

#### **DECLARATION OF COMPLIENCE WITH THE REQUIREMENTS INDICATED IN SECTION VI OF THE REQUEST FOR BIDS**

For the purposes of the contract award procedure for the implementation of a research service involving the synthesis of an active pharmaceutical ingredient (API) for the purpose of the planned research and development work and for clinical trial, as well as preparation of documentation compliant with the EU GMP regulations for this active pharmaceutical ingredient (API) necessary for the implementation of the project under working title: "*Development of an innovative drug candidate for the treatment of solid tumor metastasis to the lungs* " (Request for Bids No. 01/WPD107/2020), on behalf of the Applicant, I declare that:

Company …………………………………………………………… *(Company name)*

Registered in …………………………………………………………*(Registered Address)*

meets the following conditions:

1. I declare that we have adequate knowledge and experience within the contract object and people declare that all data contained in the Bid capable of performing the order.
2. I declare that we are in financial and economic situation that will allow the contract to be performed with due diligence.
3. I declare that:

**Package No 1:**

1. we have documented experience in the provision of services consisting on the synthesis of low-molecular weight organic compounds for the third parties, in particular experience in carrying out multi-stage (at least two-stage) synthesis of the low-molecular weight organic compounds and optimization of the process;
2. we have or will engage persons for the execution of the contract with appropriate qualifications and experience, including at least (2) two persons with specialized education (pharmacy, chemistry or related fields, i.e. medicine, biological sciences), experienced in conducting organic synthesis and technologies for the production of active substances, as well as the development and validation of analytical methods and conducting analysis;
3. we have the appropriate technical facility dedicated to the synthesis of the low-molecular weight organic compounds in septic conditions and to have certificate of the European GMP standards for the production of the organic compounds and have other required by law documents for the production, analysis and storage of the organic compounds, such as valid authorization for manufacturing of the low-molecular weight organic compounds, issued by the Main Pharmaceutical Inspectorate (for Poland) or other office appropriate for the country of residence of the Contractor.

**Package No 2:**

1. we have documented experience in the provision of services consisting of the synthesis of the low-molecular weight cytotoxic organic compounds (high potent API) in accordance with the GMP standard, intended for clinical trials for the third parties, in particular experience in conducting multi-stage (at least two-stage) synthesis of cytotoxic organic compounds and process optimization;
2. we have documented experience in development of documentation for active pharmaceuticals ingredients, in accordance with European GMP standards, including ASMF documentation, in particular module 3.S.2;
3. we have or will engage persons capable of performing the service for the duration of the contract, including: at least (2) persons with a specialized education in medicine, biotechnology, chemistry pharmacy or other related fields (e.g. biological science) having adequate knowledge and experience in the synthesis of cytotoxic organic compounds as well as in regulatory requirements and manufacturing standards for cytotoxic active pharmaceutical ingredients (including high potent APIs), and in development and validation of analytical methods and conducting analysis, as well as in preparation of registration documentation for active pharmaceutical ingredients consistent with the regulatory requirements applicable in the European Union, including EU GMP standards;
4. we have appropriate technical facility dedicated to the production of cytotoxic organic compounds (including high potent API) in septic conditions and to have certificate of the European GMP standards for the production of the cytotoxic organic compounds and have other required by law documents for the production, analysis and storage of the cytotoxic organic compounds, such as valid authorization for manufacturing of the cytotoxic organic compounds, issued by the Main Pharmaceutical Inspectorate (for Poland) or other office appropriate for the country of residence of the Contractor.

I declare that all data contained in the Bid are consistent with the actual and legal status.

Place ………………, on ……… ……..................................................

*(signature of the person(s) authorized to represent the Contractor)*